**What is in this leaflet**

This leaflet answers some common questions about TRANDATE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you receiving TRANDATE against the risks this medicine could have for you.

If you have any concerns about being given TRANDATE, ask your doctor or pharmacist.

**Keep this leaflet with your medicine.**

You may need to read it again.

**What TRANDATE is used for**

TRANDATE contains the active ingredient labetalol which belongs to a group of medicines called antihypertensives. Within this group it belongs to a class of medicines called beta-blockers. TRANDATE decreases high blood pressure by reducing the rate and force of the heartbeat and by widening arteries and helping blood flow.

TRANDATE is used for:

- rapidly lowering very high blood pressure (also called severe hypertension)
- lowering blood pressure during an operation requiring certain types of anaesthetics (drugs used to put you to sleep during the operation)
- quickly lowering high blood pressure, if necessary, after a heart attack.

Blood pressure is a measurement of the force exerted by the blood circulating in your arteries. It is shown as two values. The first measures blood pressure while the heart muscle is contracting to squeeze out blood (systolic pressure). This is the higher figure. The second measures blood pressure when the heart muscle relaxes between contractions (diastolic pressure). This is the lower figure.

Blood pressure varies from one person to the next, but usually increases as we get older. If you have blood pressure which is higher than normal when measured on three separate occasions, your doctor may diagnose hypertension. High blood pressure does not necessarily cause symptoms. However, if it is severely raised, you may get headaches and palpitations and feel quite unwell. It is important to reduce high blood pressure because it can cause stroke, heart attack, heart failure and damage to other body organs, especially the kidneys.

Ask your doctor if you have any questions about why TRANDATE has been prescribed for you.

Your doctor may have prescribed it for another purpose.

TRANDATE is available only with a doctor’s prescription, and is given as an intravenous injection by a doctor or nurse in hospital.

**Before you start being given it**

Tell your doctor if:

- you are pregnant or plan to become pregnant. TRANDATE is sometimes used to control pre-eclampsia (high blood pressure brought on by pregnancy). As with all medicines used to lower high blood pressure, TRANDATE may have unwanted effects in an unborn or new-born baby. Your doctor will weigh up the benefits of you receiving TRANDATE against the risks to your baby. If you are trying to get pregnant and need a TRANDATE injection for another condition, please tell your doctor.
- you are breastfeeding or plan to breastfeed. The active ingredient in TRANDATE, labetalol, passes into breast milk. No problems have been found in babies.
breastfed by mothers who have received TRANDATE. Do not breastfeed after receiving a TRANDATE injection until your doctor says it is all right to do so.

- you are allergic to any other medicines, insect stings, foods, dyes or preservatives. This is particularly important if you have had a sudden severe (anaphylactic) reaction to anything in the past.
- you have liver damage or liver disease
- you have heart disease, poor circulation or a blood disorder
- you have thyroid problems or are a diabetic
- you have cataracts
- you are about to have an operation which will require anaesthesia (a medicine that will put you to sleep during the operation).

If you have not told your doctor about any of the above, tell them before being given TRANDATE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including the oral contraceptive pill or medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by TRANDATE or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. These include:

- halothane
- class I anti-arrhythmic agents for irregular heart rhythms or medicines known as calcium channel blockers, which are used for high blood pressure, coronary artery disease (affecting blood vessels in the heart), and irregular heart rhythms
- non-steroidal anti-inflammatory medicines for relieving pain, stiffness and inflammation
- digoxin
- radioisotopes
- adrenaline.

Your doctor or pharmacist will be able to tell you the trade names of the above types of medicines, and about what to do when you are given TRANDATE while taking other medicines.

How it is given

How much you will be given

Your doctor will calculate your dose, depending on the reason why your blood pressure needs to be lowered and how quickly this needs to happen.

If your blood pressure needs to be lowered urgently, you may be given a bolus (concentrated dose) injection over one minute, and then repeated, if necessary, at 5 minute intervals until your blood pressure comes down. The total dose should not exceed 200 mg.

If you have pre-eclampsia (high blood pressure caused by pregnancy), very high blood pressure after a heart attack or from some other cause, or if there is a need to lower your blood pressure when you are put to sleep for an operation, you may be given a much slower continuous diluted infusion (by a drip in a vein) for up to several hours.

You should avoid sitting upright within three hours of starting a TRANDATE infusion, otherwise your blood pressure could drop down too far, making you feel very dizzy and faint.

Your doctor will do regular blood tests to make sure TRANDATE is working for you.

How it is given

TRANDATE is given in hospital as an injection into a vein by a doctor or nurse while you are lying down.

In case of an overdose

If you think that you or anyone else has been given too much TRANDATE tell your doctor or nurse immediately or call the

Poisons Information Centre (0800 POISON 0800 764 766) for advice. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose include extremely low blood pressure, a slow heartbeat, difficulty breathing and, rarely, kidney damage.

Side effects

TRANDATE is usually well tolerated. However, like all medicines, TRANDATE can have unwanted side effects. Sometimes they may be serious, but often they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Be sure that your doctor or nurse knows as soon as possible if you do not feel well when you are being given this medicine.

If you think TRANDATE is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR IMMEDIATELY.

Symptoms include:

- severe skin rash, itching or hives
- swelling of the face, lips, mouth or throat
- difficulty breathing or swallowing.

Tell your doctor or nurse if you notice any of the following:

- faintness or dizziness in the first few hours after being given a bolus injection, or after starting a slow infusion, especially when getting up from a lying or sitting position
- stuffiness in your nose
- jaundice (yellowing of your skin and/or eyes), liver problems (hepatitis)
- shortness of breath, swelling of the feet or legs due to fluid build-up (congestive heart failure)
• in men, problems with maintaining an erection.

Bradycardia (slow heart rate) and heart block (slow irregular heartbeats) have also been reported. Your doctor or nurse will be watching you carefully for signs of these.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After it is given

Storage

TRANDATE is stored in a hospital ward or pharmacy in a dry place where the temperature stays below 30°C.

Disposal

Hospital staff will dispose of any TRANDATE solution left over after your injection or infusion is finished.

Product description

What it looks like

TRANDATE is a clear, colourless liquid supplied in a glass ampoule holding 20 mL of solution.

Ingredients

Active ingredient:

Each TRANDATE ampoule contains labetalol 100 mg.

Inactive ingredients:

• dilute hydrochloric acid or sodium hydroxide
• water for injections.

Distributor

Distributed in New Zealand by:

Pharmacy Retailing Pty Ltd
t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland

This leaflet was prepared in January 2012.